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ADVANCING DENTISTRY

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510(k) Summary Statement for the Texas Institutes' CleanAir/CleanWater™ Unit

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I. General Information

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Contact Persons:	J Tim Rainey, D.D.S. – Developer/Inventor H. O. Pipkin – Managing Director
Summary Preparation Date:	October 10, 2000
Name & Address of Manufacturing Facility:	Same As Above

II. Names

Device Name:	CleanAir/CleanWater™ unit.
Primary Classification Name:	Dental Operative Purified Water System with Independent Reservoirs

III. Predicate Devices

Self-Contained Water Systems (DCI, International), FDA #K944271

Porta Purge (Micrylium Laboratories), FDA #K973765
Dispenser System for Handpiece Lubricating Coolant (DCI, International), FDA #944271
Steriwater System (Waggoner), FDA #K925829

IV. Product Description

The Texas Institutes' CleanAir/CleanWater™ unit currently utilizes an existing FDA cleared Self-contained Water Systems marketed by DCI International and equivalent to the DCI International Self-contained Water Systems. Instead of the common remote single fluid manifold or split line manifold system used in most dental applications (where a single line is split off by "Y's" and thus becomes a delivery manifold), an equivalent single common manifold is provided. By providing two fluid bottle units and connecting both fluid bottle units to a common manifold through three-way switches, the end user, Dentist, Hygienist, or other professional, can simultaneously choose a variety of combinations of delivery of purified water or disinfectant to a variety of instruments.

The unit relies on two three-way switches, a common, centrally located one piece manifold, very small (1/16") DUWL's, and very short distances to attain a very practical and fast access in delivering the disinfectant to the point-of-use. When switching back and forth between clean water and disinfectant on instruments connected to the second manifold bar, the previous fluid is purged almost instantly because of the small volume of fluid resident in the manifold and 1/16" DUWL's. Although equivalent features do exist on other units, the use of small 1/16" DUWL's contributes to an ease and economy of use unique to this unit.

The unit also addresses an often-overlooked source of local contamination, and that is the quality of the incoming air. (See 1,2) The air decontamination point-of-use filter unit has a common .22 micron biological particle filter used in the wine industry in a coalescing filter body to remove oil mist, visible water mist, and

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(1) Bjerring P, Oberg B. Bacterial contamination of compressed air for medical use. Anesthesia 31:148-150, 1986.
The present study demonstrates a previously unnoticed source of bacterial contamination of locally manufactured compressed air for medical use. Air samples were drawn into a specially constructed device, and bacterial contents were identified from growth on agar plates. Various factors contributing to bacterial contamination of compressed air during production are mentioned and preventive measures are discussed.

(2) Compressed air - status report '96. Clinical Research Associates Newsletter 1996:20(8)

particulate matter. With a clear, drainable polycarbonate bowl and an easily accessed and changeable filter, the caregiver can easily visually monitor the quality of the incoming air supplying the total dental unit and easily change the filter on a regular basis. Although accumulative equivalent features do exist on many cleared-to-market dental units, this common sense combination of features in a single location is missing on virtually all other units now currently on the market which have site specific applications rather than addressing the entire needs of the dental unit in a single location.

The Texas Institutes' CleanAir/CleanWater™ unit is comprised of the following main components:

- **A three-way on/off/bleed switch on the incoming pressurized airline.**
- **A high-pressure air regulator and gauge.**
- **A point-of-use .22-micron biological particle filter and coalescing filter bottle.**
- **A four bar manifold with four check valves on the incoming fluid side.**
- **A low-pressure air regulator and gauge.**
- **Two fluid bottles with three way switches.**
- **Large diameter (1/4") DU fluid lines for high volume and high air pressure.**
- **Small diameter (1/16") DU fluid lines for low-pressure air, clean water, and disinfecting fluid.**
- **A mounting box and appropriate mounts for all components.**
- **An optional three-way switch for incoming city water appropriately disinfected.**

V. Indications for Use/Rationale for Substantial Equivalence.

1. Any equipment connected to the unit manifold can be easily purged at the end of the day by flipping both fluid switches to the "Fore"(Flush) position.

2. Equipment and procedures benefiting from optional delivery of a disinfectant can be supplied appropriately and almost instantly with the flip of a single switch during clinical procedures.

3. The average patient assumes that the dentist is using potable quality water in their treatment. When a dental patient is asked if they mind a dentist using sewer quality water in their mouths, the average patient finds the thought revolting. "Water that is unfit to drink is unsuitable for therapeutic use in dentistry. Continued inaction of the part of the dental profession can serve only to undermine public confidence in our commitment to quality dental care."(See 3) The rationale

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(3) Mills SE; The dental unit waterline controversy: defusing the myths, defining the solutions. JADA 131:1440, 2000

and mindset against purified water systems is identical to the resistance dentists expressed when the profession was slowly switching to gloves in the early 1980's.

Rational for Substantial Equivalence:

All of the parts and all applications in the CleanAir/CleanWater™ Unit are currently being used in some combination in similar units. By splitting the delivery lines with typical "Y's", in common use, the manifold system can be duplicated. Excluding the manifold, and point-of-use filter, this two-bottle unit can be assembled by purchasing three single bottle systems, then disassembling and reassembling most of the individual components into a two-bottle system. (Or completely duplicated by adding the point-of-use filter.) The equivalent system can also be provided by installing three single bottle delivery systems and duplicating key equipment in a single operatory (two ultrasonic units, two ProphyJets, two highspeed handpieces, three air/water three-way syringes, each connected to a Purified Water or Disinfectant Fluid unit). Although equivalent in function to this duplicity of equipment, this is the only unit that puts the parts and the connected equipment in a common sense package easily monitored and controlled by the operator.

There are flushing devices with switches that allow the professional caregiver to switch back and forth between city water and handpiece lubricating coolant (DCI's dispenser system for handpiece lubricating coolant). There are manual flushing devices designed to be used at the end of the day (Micrylium's Porta Purge). However, most disinfecting of dental systems is designed to take place as an end-of-day procedure with the disinfectant working overnight. This CleanAir/CleanWater™ system offers the equivalent of both, allowing almost instant switching between purified water and disinfectant, and then allowing purging of the entire fluid system at the end of the day.

Some offices prefer to leave the disinfectant in a purge bottle, allowing a choice of using a disinfectant or bottled water. Although equivalent in part to the Texas Institutes' CleanAir/CleanWater™ system, the use of this type of single bottle system requires the use of incoming city water interspersed with intermittent use of disinfectant. Unless the dentist duplicates equipment in single operatories, the caregiver would not have the choice of simultaneously using purified water while simultaneously providing a disinfectant as a handpiece lubricating coolant to an operating field.

If the unit is plumbed with a single bottle system and typical ¼" Dental Unit Water Lines. there is also a tremendous time lag between flipping the switch and the actual delivery of the disinfectant and then another time lag between switching back to water and the actual purging of the disinfectant from the DUWL's. The volume of fluid delivered through 1/16" lines versus the standard ¼" lines is equivalent. although the time lag factor when switching between fluids is virtually eliminated due to the reduction by a factor of 16:1 of volume of fluid occupying

the lumen of the smaller line.

There are a number of air filtration devices on the market, but unless the dentist is diligent in the maintenance of these typically hidden devices they will eventually become contaminated. Out of sight seems to imply out of mind in the dental field. (My original DCI single button syringe had a filter that used a common cotton roll in a cartridge hidden in the handle. My incoming air filter in my Executive dental unit is under the unit. There were no provisions to maintain this filter on a regular basis. It cannot be monitored visually, and it is difficult to get to). There are numerous point-of-use air filters for sale and in use on dental units. None are designed to be the sole point-of-use filter for the entire unit **AND** easily monitored and serviced.

Summary: Description of the Texas Institutes' CleanAir/CleanWater™ Delivery system

I. The manifold has four rows of holes or "Bars". All bars are charged from the right hand side through one-way check valves.
   1. The top bar is for water fluid delivery.
   2. The second bar is for disinfecting fluid delivery. (i.e. Bio 2000)
   3. The bottom two bars are for purified air.

II. There are two "Fluid" bottles.
   1. The Left bottle is for purified water
      A. This bottle charges the top bar of the manifold through the top right side fluid check valve.
   2. The Right bottle is for disinfectant. (Bio 2000)
      A. This bottle charges the second fluid bar through the second fluid check valve.

III. There are two fluid switches, one for each fluid bottle mount, which is the equivalent of the top-of-bottle mount switches.
   1. There are only four possible combinations of positions for these switches
      A. Both switches in the H2O ("Aft") Position marked H2O.
         1. This position charges both fluid bars with water.
      B. The left switch in the H20 ("Aft") Position and the right switch in the Flush ("Fore") Position.
         1. This position charges the top fluid bar with H2O and the second fluid bar with Disinfectant (Bio 2000)
      C. FLUSH. Both switches in the Flush ("Fore") position
         1. **FLUSH** position charges both bars with Disinfectant
            a. This position is used at the end of the day to disinfect all fluid lines.
      D. NEUTRAL. Right switch in the Flush ("Fore") position, Left switch in the H20 ("Aft") Position". This position neutralizes right and left bottle flow,

and there will be no fluid delivered from this position.

IV. There is an on/off switch controlling incoming air. This air pressurizes the system.
1. The high-pressure regulator pressurizes the fourth bar of the manifold. Any equipment needing high-pressure air, i.e. a single button bonding air syringe or a high-speed handpiece will be supplied through this bar.
2. The low-pressure regulator pressurizes the third bar of the manifold. Any equipment needing low-pressure air, i.e. the fluid bottles, three-way syringes, etc. are connected to and pressurized from this bar.

V. There is an on/off switch in the fluid line. This switch can be a three-way switch allowing bypass of the purified water bottle by incoming appropriately purified water.

The end user must insure that any water bypassing the purified water bottle is appropriately purified.

This device provides simplicity of use while sharing the same indications for use, similar and identical materials, design, operational, functional, and disinfecting features and, therefore, is substantially equivalent to the predicate devices listed in section III of this summary.

VI Safety and Effectiveness Information

Safety and Effectiveness are demonstrated by:

- **Performance testing after assembly to confirm that switching mechanism is working and properly assembled.**
- **Confirming the patency of all connections with brushed on water.**
- **Regulating incoming air and monitoring air pressure via high-pressure air gauge.**
- **Same indications for use as predicated devices.**
- **Same disinfecting solutions as used in predicated devices.**
- **Fluid bottles are High Density Polyethylene (HDPE) bottles with a rated burst pressure of 200 PSI.**

All the above steps and evaluations combine to demonstrate that the Texas Institutes' CleanAir/CleanWater™ Unit is safe and effective when the device is used as labeled.

VII Conclusion:

The Texas Institutes' CleanAir/CleanWater™ Unit was found to be substantially equivalent to

the predicate devices; Self-contained water system (DCI, International), Porta Purge (Micrylium Laboratories), Dispenser system for handpiece lubricating coolant (DCI, International), Steriwater system (Waggoner). The Texas Institutes' CleanAir/CleanWater™ Unit shares the same indications for use, similar materials, design, operational, and functional features as the current marketed predicated devices and is designed to use similar disinfecting solutions designed for purging DUWL's and dispensing handpiece lubricating coolant. It has been shown to be safe and effective when used as labeled.

(End)

Roman Numeral VIII in Table of Contents:

Performance Standards: Operating the Texas Institutes' CleanAir/CleanWater™ Delivery system

The Texas Institutes' CleanAir/CleanWater™ delivery system performs as a combination purified water unit and disinfectant/handpiece, lubricant/coolant unit powered by filtered incoming compressed air.

The incoming air first enters a three-way on-off-bleed air switch, and then is regulated to a manageable level for typical dental rotary handpiece applications. The air then enters the coalescing/particulate filter bowl assembly. The first stage of regulated clean air is then used to pressurize the high-pressure bar of the air manifold. A line tapped into this bar leads to a pressure gauge to allow monitoring of the regulated incoming high air pressure. This bar has multiple taps. It is typically used to drive instruments requiring high volumes of high-pressure air; i.e. rotary high-speed handpieces, which typically have a second and independent regulator in the drive system. A dentist will also typically tap into this line for pressurizing a single button air syringe to deliver high volumes of clean air during bonding procedures. The air exits this manifold, is delivered to the low-pressure regulator, and pressurizes the low-pressure bar of the manifold.

The low-pressure bar has multiple taps also. A line tapped into this bar leads to a pressure gauge to allow monitoring of the low-pressure bar. Instruments typically needing lower pressure for patient comfort, such as the fluid bottles and three-way air/water/spray syringes are pressurized by this bar.

There are two fluid bars in the manifold. The Left Fluid bottle is typically designated as the purified water bottle, while the Right Fluid bottle is designated as the disinfecting fluid bottle. It is expected of the dentist to disinfect and recharge the purified water bottle daily with purified water. The bottle is easily disinfected by simply pouring the water from this bottle after the daily purge of all systems, drying the bottle, and then filling this bottle with the next day's disinfectant and switching this bottle to the right fluid bottle position. The disinfectant bottle is then left to drain overnight and then is filled in the morning with purified water and switches position by becoming the left side purified water bottle.

The water from the left purified water bottle typically pressurizes the top bar of the two bar fluid manifold. For example, the non-surgical three-way syringe is typically pressurized from this bar.

The lower bar of the two bar fluid manifold is pressurized directly from the Right bottle containing disinfectant. This fluid line leading to the lower bar is intercepted by a three-way switch which is also supplied by a fluid line leading from the top bar. This gives the professional caregiver an option of connecting equipment that can be used with either purified water or disinfectant, such as the surgical three-way syringe, or an aerosol forming unit such as the ultrasonic scaler or high speed handpiece. By flipping this controlling switch back and forth, the professional can switch back and forth almost instantly between disinfectant or purified water. At the end of the procedure, the three-way syringe fluid line attached to this unit can be almost instantly purged with disinfectant.

Sincerely,

J Tim Rainey, D.D.S., M.A.G.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2000

Mr. H.O. Pipkin
Managing Director
Texas Institute For Conservative Dentistry
702 Osage Street
Refugio, Texas 78377

Re: K003265
Trade Name: Cleanair/ Cleanwater Unit, Model 1600
Regulatory Class: I
Product Code: EIA
Dated: October 10, 2000
Received: October 18, 2000

Dear Mr. Pipkin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CleanAir/CleanWater™ Unit

INDICATIONS FOR USES

1. The Texas Institute's CleanAir/CleanWater™ Unit is indicated for use in general dentistry and dental hygiene. This unit is intended to provide a method to isolate Dental Unit Water Lines from municipal water sources and give the dentist options of irrigant fluids.

2. This unit is indicated for use where it is desired to deliver purified air and purified water to an operating dental environment.

3. This unit is indicated where purging of DUWL's with a disinfectant or a lubricant is desired that is biocompatible with the human oral environment.

4. This unit is indicated for use during procedures where simultaneous delivery of two different fluids is desired.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003265